HUMAN SUBJECTS OFFICE (HSO)
DOCUMENTATION OF EXEMPTION DETERMINATION FOR PROTOCOL

Date Rec'd in HSO _____

Instructions: Use this form when submitting a request for exemption from 45 CFR 46. Please submit this form electronically along with the protocol (or project description) and any supporting documents to the CIO designated staff official. However, if submitted in hardcopy, please send the original to the Human Subjects Office through the CIO designated staff official. Consecutively number **ALL** pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted by Investigator: _____

PROTOCOL NO. _____
(For Human Subjects Office Use)

Title of Protocol: _____

Proposed Dates for Project - Begin: _____ End: _____

Name of CDC Employee Serving as Principal Investigator (PI) and Degrees:

_____

9 Check if PI has changed

Scientific Ethics Verification No.: _____ Telephone: _____ Fax: _____

CIO: _____ **Division**: _____ **MS**: _____ Email Address: _____

Names of Other CDC Employee Co-investigators (use supplemental page if > than 3):

1. _____ *Scientific Ethics* Verification No.: _____

2. _____ *Scientific Ethics* Verification No.: _____

3. _____ *Scientific Ethics* Verification No.: _____

STUDY POPULATION (If an international study, provide race/ethnicity of subjects by estimated percentages):

_____

Estimated Number of Subjects: _____

Gender distribution:
_____ % Female _____ % Male

Race/Ethnicity distribution for domestic studies:
_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander
_____ % Black or African American; not of Hispanic Origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

FUNDING (check one)

_____ PGO Funding Mechanism Used:

_____ Cooperative Agreement No(s).: _____

_____ Contract No(s).: _____

_____ Grant: _____

_____ Purchase Order (a.k.a. Simplified Acquisition): _____

_____ Other Funding Mechanism:

_____ Memorandum of Understanding (MOU) (with whom): _____

_____ Interagency Agreement (IAA) (name of other agency): _____

_____ Other (specify type and with whom): _____

_____ Only CDC investigators performing study

_____ Collaborative (Non-CDC Investigators & CDC investigators; no funding involved)

LOCATION OF THIS RESEARCH (Use additional sheets if necessary)

_____ U.S. or its territories? _____ Foreign country (countries)?

List All Collaborating Sites by Full Name and Location (include state):	**OPRR Assurance No.:**
1.	
2.	
3.	
4.	
5.	

The Federal Regulations, under §46.101, establish categories of research that are exempt from the requirements set forth in 45 CFR 46. To determine whether the proposed research is exempt under one of these categories, please COMPLETE EACH SECTION BELOW.

Does the proposed research involve prisoners?

YES _____ **This research cannot be exempted under any category listed below. All research involving prisoners must be reviewed by an IRB.**

NO _____

Does the proposed research involve fetuses, pregnant women, or human in vitro fertilization as TARGETS (such that Subpart B would apply)?

YES _____ **This research cannot be exempted under any category listed below. All research involving fetuses, pregnant women, or human in vitro fertilization must be reviewed by an IRB.**

NO _____

1. <u>Educational Research</u>: Is this research conducted in established or commonly accepted education settings, AND does the research involve normal educational practices (e.g., research on regular and special education strategies or research on the effectiveness of, or comparison among, instructional techniques, curricula or classroom management methods) ?

YES _____

NO _____

2. <u>Research Involving Surveys, Interview Procedures (including Focus Groups), Observations of Public Behavior, or Educational Tests:</u> Will this research use educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?

YES _____

NO _____

2.1 Will children (17 years of age or younger) be research subjects?

YES _____ IRB review is required unless exempt under §46.101(b)

NO _____

2.2 Is the information recorded in such a manner that human subjects can be identified <u>directly or indirectly</u> through identifiers (such as a code) linked to the subjects?

YES _____

NO _____

2.3 Will any disclosure of the human subjects' responses outside of the research setting have the potential to place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability or reputation? (Examples here include: the collection of sensitive data regarding the subjects' (or relatives' or associates') possible substance abuse, sexuality, criminal history or intent, medical or psychological condition, financial status, or similarly compromising information).

YES _____

NO _____

2.4 Are the human subjects elected or appointed public officials or candidates for public office?

YES _____

NO _____

2.5 Does federal statute(s) require(s), without exception, that confidentiality of the personally identifiable information will be maintain throughout the research and thereafter? (Note: CDC can use this exemption criterion only in the case where a 308(d) Assurance of Confidentiality has been obtained to cover the research).

YES _____

NO _____

3. <u>Existing Data Which Is Publicly Available or Unidentifiable:</u> Does this research involve the collection or study of existing* data, documents, records, pathological or diagnostic specimens? (*"existing" means the data were available before the study begins.)

YES _____

NO _____ Skip to 4

3.1 Is this material or information publicly available?

YES _____

NO _____

3.2 Is this material or information recorded in such a manner by the investigator that the subjects cannot be identified <u>directly or indirectly</u> through identifiers linked to the subjects? (Note: If a link is created by an investigator, even temporarily, for research purposes, this criterion is not met. If a temporary link is created by clinical staff who already have access to the data, this criterion is met.)

YES _____, there is no identifying information and no unique identifiers or codes.

NO _____, there are identifiers (including codes).

4. <u>Public Benefit or Service Programs</u>: (Note: At the present time, CDC does not have authority to use this exemption category; however if you think your research would qualify, please discuss with the Human Subjects Office).

Is this research or demonstration project conducted under the approval of the Secretary of DHHS and designed to study, evaluate, or examine:

1. Public benefit or services programs,
2. Procedures for obtaining benefits or services under these programs,
3. Possible changes in or alternatives to these programs, or
4. Possible changes in methods or levels of payments for benefits or services under these programs ?

YES _____

NO _____

5. <u>Food Research:</u> Is this a taste or food evaluation or a consumer taste or food acceptance study?

YES _____

NO _____

5.1 Will only wholesome foods without additives be consumed OR will any food ingredients (including additives) consumed be demonstrably at or below the level, and for a use found to be safe, or agricultural chemical or environmental contaminants demonstrably at or below the level found to be safe, by the Food and Drug Administration or approved by the Environment Protection Agency or the USDA Food Safety and Inspection Service?

YES _____

NO _____

Please attach a brief (1-2 pages) description (should include research questions, study population, design and methods in sufficient detail to make a determination about exemption status) or protocol (if available) for the research study. Please include an explanation of why this project is exempt.

Approvals (Signature and Position Title): Branch Chief:	**Date:**	**Remarks:**
Division Director:		
CIO Human Subjects Contact:		